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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/035,708 | 03/05/1998 | FRANK P. ZEMLAN | 91830 | 5121 |

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| EXAMINER |
|---|
| HAYES, ROBERT CLINTON |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 39 |

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/035,708 | Zemlan et al |
| **Examiner** | **Art Unit** |
| Robert C. Hayes, Ph.D. | 1647 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Dec 17, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-14, 17, 19-24, 26, 27, 29, 32, and 33* is/are pending in the application.

4a) Of the above, claim(s) *1-13, 21, and 22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14, 17, 19, 20, 23, 24, 26, 27, 29, 32, and 33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-14, 17, 19-24, 26, 27, 29, 32, and 33* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *37*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 12/17/02 has been entered.

2. Applicants' arguments filed 12/17/02 have been considered but are not found persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The Declaration under 37 CFR 1.132 filed 12/17/02 is insufficient to overcome the rejection of claims 14, 17, 19-20, 23-24, 26-27, 29 & 32-33 based upon being anticipated by Vandermeeren et al (WO 94/13795) under 35 U.S.C. 102(b) as set forth in the last Office action because Declarant's "opinion" (i.e., see page 2, line 6) is not on point with the rejections made of record, nor for what the claims alternatively legally encompass. For example, Declarant's statement that "the Examiner's speculation with regards to Alzheimer's Disease causing head trauma" is a clear mischaracterization of the record. The issue is two-fold. First, the broad and generic recitation of "traumatic head injury/cerebrovascular accident" encompasses all injured neurons in the "head", including those affected during Alzheimer's disease, because Applicants have failed to define what this term means in the specification (e.g., see new matter rejction below). Second, Declarant's statement that "*[a]lmost*, no major traumatic brain injuries are...

due to falls which are secondary to Alzheimer's dementia" alternatively support the rejection made of record, in which Alzheimer's patients are reasonably part of the population that experiences "traumatic head injury/cerebrovascular accident", etc., as currently claimed, because no one skilled in the art would ever reasonably conclude that Alzheimer's patients never experience "traumatic head injury/ cerebrovascular accident", which unfortunately frequently occurs in the aged population; especially as it relates to "gait stability... in the very latest stages of the disease", as correctly argued by Declarant.

As previously made of record, the issue remains that central nervous system basal forebrain cholinergic neurons affected during Alzheimer's disease are in the "head", and the broad and generic recitation of "traumatic head injury/cerebrovascular accident" encompasses all injured neurons in the "head", including those affected during Alzheimer's disease (i.e., especially as it relates to "secondary traumatic lesions", as also argued by Declarant). Again, because it is the instant specification itself that fails to provide a definition for the recitation "traumatic head injury", because the term "traumatic head injury" has multiple meanings, because "gait stability... in the late stages of the disease" would reasonably lead one skilled in the art to at least initially "*suspect* [one] of having traumatic head injury"[emphasis added], as currently claimed, and importantly because each and every step in Vandermeeren's method is otherwise equivalent to the method currently claimed, Vandermeeren's method clearly anticipates the claims, for the reasons extensively made of record. See also *Ex parte Novitski,* 26 USPQ2d 1389 (BPAI 1993).

5. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 35 (mailed 8/16/02), and as follows.

Applicants argue on page 1-3 of the response that proper antecedent basis exists for new claims 31, etc. on pages 4-5 of the specification, and that "the term[s] 'head injury' or 'a method of determining axonal damage in the head'... are not used in claims 32 or 33 to define the scope of the invention". In contrast to Applicants' assertions, this is a clear misrepresentation of what even claims 32 & 33 recite, in that these terms are still recited in claims 32 & 33, as also is the case in base claim 14, as previously made of record. Additionally, Applicants' insistence on mix and matching different terms to putatively overcome the art made of record (i.e., as it relates to the term, "traumatic head injury",etc.), and that described on pages 2, 3, 4 & 5, still do not obviate the requirements under 35 U.S.C. 112, first paragraph, as it relates to new matter, for the reasons previously made of record, which is consistent with that held by the courts in *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, which makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]". It is noted that Applicants' arguments regarding "assays" are further not on point, and do not address the rejection of record, and that

Applicants' assertions that "[w]hether those terms are used in the application in the context ... does not matter" is simply wrong.

No proper antecedent basis nor conception within context of that disclosed within the specification at the time of filing the instant application further exists for the new and broader recitation of "**traumatic head injury** is selected from primary hemorrhages, primary vascular injuries, *traumatic lesions*, and acute cerebral vascular accident" (i.e., as it relates to new claim 33). Similar to that previously made of record and in contrast to Applicants' assertions, no proper basis exists on pages 4-5 of the specification, which alternatively is directed to the different concept of:

> "[t]he method of the instant invention may be used to determine whether *axonal damage has occurred* and to what extent, and thus can be used to determine the existence or likelihood of any disease *associated with axonal damage, such as* ... primary hemorrhages..., primary vascular injuries..., *cranial nerve injuries and secondary* traumatic lesions..., *neurodegenerative diseases of the central nervous system including Alzheimer's disease...* , acute cerebral vascular accident *or axonal damage following ingestion of drug(s) or poison(s)* [emphasis added]";

thereby, constituting new matter.

6. Claim 20 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It remains ambiguous what metes and bounds entail the recitation "said... tau protein *lacks the native N-terminal and C-terminal amino acids"*, in that it is ambiguous whether one or

more amino acid residues are envisioned to be removed, and if so, where exactly does the N-terminus and the C-terminus ends.

Applicants' arguments regarding "a quick computer search...", etc. do not address the rejection made of record, and therefore, are moot.

7. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in Paper NOs: 12 (mailed 1/24/00), 17 (mailed 8/16/00), 25 (mailed 7/23/01), 28 (mailed 1/02/02) & 35 (mailed 8/16/02), and as follows.

It is noted that Applicants' arguments on pages 3-4 of the response have either been addressed in the previous Office action, or addressed above in *pp#* 4 above. See also *Ex parte Novitski,* 26 USPQ2d 1389 (BPAI 1993), which held that:

"although [the prior art reference] does not disclose the claimed method *in haec verba*, it does disclose [a] method....., which inherently possesses... [the claimed] activity. It is axiomatic that the claims define the patent grant, and it is the function of the claims to patentably define appellants' invention over the prior art."

In other words, Alzheimer's patients inherently are part of the population of patients with "traumatic head injury" (i.e., as it relates to claims 33) or "axonal damage in the head of a patient suspected of having traumatic head injury/ a cerebrovascular accident" (i.e., as it relates to claims 14 & 32), as further supported in the 12/17/02 declaration (i.e., see page 3)).

Again note MPEP 608.01 (o)), in regards to the breadth encompassed by any term. Note further that Vandermeeren teach each and every limitation recited in the claims, as previously made of record, and that in contrast to Applicants' arguments, "hindsight" is not a consideration under 35 U.S.C.102; thereby, making Applicants' arguments moot.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
March 26, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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